In the Claims

Please amend the claims by replacing all prior listings of claims with the listing of claims below pursuant to 37 C.F.R. §1.121:

1-11. (Canceled)

12. (Currently Amended) A pharmaceutical composition comprising

an aqueous carrier;

from 0.1 mg/ml to ~~20~~ 2.5 mg/ml of the composition of an acetate salt of a peptide having the structural formula

NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

from 70 mg/ml to 170 mg/ml of the composition of hepta-(sulfobutyl ether)-β-cyclodextrin or a salt of hepta-(sulfobutyl ether)-β-cyclodextrin,

wherein the peptide and the hepta-(sulfobutyl ether)-β-cyclodextrin or a salt of hepta-(sulfobutyl ether)-β-cyclodextrin are dissolved in the aqueous carrier; and

wherein the pharmaceutical composition has a pH between 6.5 and 8.5.

13. (Original) The pharmaceutical composition of claim 12, wherein the concentration of the acetate salt of the peptide is at least 0.5 mg/ml.

14. (Canceled)

15. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 to 2.5 mg/ml.

16. (Currently Amended) The pharmaceutical composition of claim 13, wherein the concentration of the salt of hepta-(sulfobutyl ether)-β-cyclodextrin is 120 mg/ml, and wherein the pH of the pharmaceutical composition is between 7.5 and 8.5.

17. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 1.0 mg/ml.

18. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 2.5 mg/ml.

19. (Currently Amended) A method of alleviating symptoms of systemic lupus erythematosus (SLE) in a human subject comprising administering to the human subject the pharmaceutical composition of claim ~~1—~~12 in an amount effective to alleviate the symptoms of SLE in the human subject.

20. (Canceled)

21. (Currently Amended) A process for manufacturing the pharmaceutical composition of claim ~~1—~~12 comprising the

steps of:

a) preparing a solution of a substituted β-cyclodextrin or a salt thereof in an aqueous carrier at a predetermined concentration;
b) adding a predetermined amount of a pharmaceutically acceptable salt of the peptide NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1) to the solution of step a);
c) adjusting the pH of the solution of step b) until the peptide dissolves in the solution; and
d) if necessary, adjusting the pH of the solution of step c) to a pH of 4-9, thereby manufacturing the pharmaceutical composition.

22-30. (Canceled)

31. (Previously Presented) A pharmaceutical composition prepared by the process of claim 21.

32. (Currently Amended) A process of lyophilizing the pharmaceutical composition of claim ~~21~~12, comprising the steps of:
a) lowering the temperature of the pharmaceutical composition to -40°C;
b) holding the temperature at -40°C for a predetermined time;
c) raising the temperature of the solution to 20°C;
d) holding the temperature at 20°C for a predetermined time; and

e) reducing the pressure in step d) to a pressure suitable for lyophilization and holding the temperature at 20°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

33-40. (Canceled)

41. (Original) The process of claim 32, wherein
step a) is performed within 2 hours;
step b) is performed within 3 hours;
step c) is performed over 13 hours and at a pressure of 110μbar;
step d) is performed over 13 hours and at a pressure of 110μbar; and
step e) is performed over 5 hours and the pressure is reduced to 10μbar.

42. (Previously Presented) A lyophilized pharmaceutical composition prepared by the process of claim 32.

43. (Currently Amended) A process of lyophilizing the pharmaceutical composition of claim ~~2~~12, comprising the steps of:
a) lowering the temperature of the pharmaceutical composition to -45°C;
b) holding the temperature at -45°C for a predetermined time;
c) raising the temperature of the solution to -20°C;
d) raising the temperature of the solution to 25°C; and

e) holding the temperature at 25°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

44-51. (Canceled)

52. (Original) The process of claim 43, wherein
step a) is performed within 6 hours;
step b) is performed within 3 hours;
step c) is performed over 19 hours and at a pressure of 150μbar;
step d) is performed over 13 hours and at a pressure of 150μbar; and
step e) is performed over 8 hours and at a pressure of 150μbar.

53. (Original) A lyophilized pharmaceutical composition prepared by the process of claim 43.

54-56. (Canceled)

57. (Currently Amended) A lyophilized pharmaceutical composition comprising
a pharmaceutically acceptable salt of a peptide having the structural formula
NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and
a ~~substituted~~ hepta-(sulfobutyl ether)-β-cyclodextrin or a salt thereof.

58. (Previously Presented) A packaged pharmaceutical composition comprised of:
a packaging material; and
the lyophilized pharmaceutical composition of claim 57.

59. (Previously Presented) The lyophilized pharmaceutical composition of claim 53, wherein the water content of the pharmaceutical composition is less than 5%.

60. (Previously Presented) The lyophilized pharmaceutical composition of claim 59, wherein the water content of the pharmaceutical composition is less than 4.0%.

61. (Previously Presented) The lyophilized pharmaceutical composition of claim 60, wherein the water content of the pharmaceutical composition is less then 3.5%.

62. (New) The pharmaceutical composition of claim 12, wherein the pharmaceutical composition is iso-osmotic.

63. (New) The pharmaceutical composition of claim 12 formulated for subcutaneous administration.

64. (New) The pharmaceutical composition of claim 12 further comprising HCl or NaOH.

65. (New) The pharmaceutical composition of claim 12 wherein the salt of hepta-(sulfobutyl ether)-β-cyclodextrin is a sodium salt.